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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/663,212	09/15/2003	Jack A. Dant	1292.1225101	2345

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EXAMINER

SWIGER III, JAMES L

ART UNIT	PAPER NUMBER
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3733

MAIL DATE	DELIVERY MODE
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10/01/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.		Applicant(s)	
	10/663,212		DANT, JACK A.	
	Examiner		Art Unit	
	JAMES L. SWIGER III		3733	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 August 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4, 6-11, 14-16, 18-22, 28 and 29 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4, 6-11, 14-16, 18-22, 28 and 29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 9/19/2008 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 8/29/2008 has been entered.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3-4, 6, 9, 11, 18-19, 21-22, and 28-29 are rejected under 35 U.S.C. 102(b) as being anticipated by Burgin (US 4,156,424). Burgin discloses a device for distraction, capable of distracting vertebrae due to its various sizes (see Col. 6, lines 35-42), comprising a base (18 and 24) and a first and second paddle coupled to the base (64), and wherein the paddles are pivotal from a first to a second orientation. The device of Burgin further discloses a pivot hinge (58) that connects both the first and second paddles to the base portion, and at opposing ends, and wherein the paddles have rounded ends (see near 64 in Fig. 1), and wherein either of the paddles could be capable of being a lordotic paddle, as it appears to have a curved profile in Fig. 1 to

address the Lordotic curvature. Burgin further disclose a bridge portion that extends between the base portion (26) wherein the paddles are capable of moving relative to the bridge portion in an open and closed position, and wherein the paddles are adapted for insertion between adjacent vertebrae prior to distraction in a closed position. With regard the statement of intended use and other functional statements, such as that the device is capable of distraction in a direction that is generally perpendicular to the plane between the horizontal axes (e.g. separating the vertebrae), they do not impose any structural limitations on the claims distinguishable over Burgin '424 which is capable of being used as claimed if one so desires to do so. *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). Furthermore, the law of anticipation does not require that the reference "teach" what the subject patent teaches, but rather it is only necessary that the claims under attack "read on" something in the reference. *Kalman v. Kimberly Clark Corp.*, 218 USPQ 781 (CCPA 1983). Furthermore, the manner in which a device is intended to be employed does not differentiate the claimed apparatus from prior art apparatus satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQ2d 1647 (1987).

In further comparing and open and closed position, the device of Burgin is further capable of having its paddles being pivotal from a generally horizontal axis to an approximately perpendicular axis. At least portion 66 of the paddles can be considered horizontal, depending on how one looks at the device and from what point it is considered open and closed. The paddles connected to the base portion may be pivoted to a position wherein the paddles are approximately parallel to the base in a

horizontal orientation and to another position where they may be perpendicular to the base (see Fig. 1, they may be rotated as such relative to the base). The parallel position can be considered a closed position and the perpendicular can be considered an open position and the body is capable of distracting. Also, depending on how one views the device the paddles can be considered either less or more upright. Additionally at least the curved portion of the paddle portion may be considered at least a major face that faces the bridge in the closed position and towards each other in the open position.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Burgin '424 in view of Brantigan (US 5,425,772). Burgin discloses the claimed invention except for the paddles being radiolucent. Brantigan disclose an implantable device for the spine that may be made of a radiolucent material (Col. 1, lines 23-24). It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the device of Burgin having at least a paddle portion made of a radiolucent material in view of Brantigan to better guide the device in use in the spine.

Claims 14 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Burgin '424 in view of Baynham et al. (US 6,224,599). Burgin discloses the claimed

invention except for the paddles and bridge member defining a portal window when they are in an open position that define a sight line. Baynham et al. disclose a wedge portion that can create a 'window' for use in accessing the spinal area for distraction (see Fig. 5, and Col. 2 lines 15-35). It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the device of Burgin having at least a wedge distractor window area in view of Baynham et al. to better access the spinal area in use of the device.

Claims 2, 16, and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Burgin '424. With regard to claims 2 and 16, it would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the first and second paddles having a height in the range of 4 to 18 mm, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

Claims 7 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Burgin '424. Burgin discloses the claimed invention except for the first paddle having surface irregularities and serrations. It would have been an obvious matter of design choice to one skilled in the art at the time the invention was made to construct paddle having surface irregularities and serrations, since applicant has not disclosed that such solve any stated problem or is anything more than one of numerous shapes or configurations a person ordinary skill in the art would find obvious for the purpose of

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providing paddle with said surface modifications. In re Dailey and Eilers, 149 USPQ 47 (1966).

Response to Arguments

Applicant's arguments and amendments filed 8/29/2008 for claims 1-4, 6-11, 14-16, 18-22, and 28-29 have been considered but are not persuasive.

It is noted that the prior art still read on the instant claims and that the device of Burgin would be capable of distracting vertebrae in a claimed axial direction if one chooses to do so. It is considered a functional limitation.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. See PTO-892.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JAMES L. SWIGER III whose telephone number is (571)272-5557. The examiner can normally be reached on Monday through Friday, 9:00am to 5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/JAMES L SWIGER/
Examiner, Art Unit 3733

/Eduardo C. Robert/
Supervisory Patent Examiner, Art Unit 3733